

Written Testimony
Heather Cianfrocco, CEO Optum Rx
Senate HELP Committee Hearing
“The Need to Make Insulin Affordable for All Americans”
May 10, 2023

Chairman Sanders, Ranking Member Cassidy, and Members of the Committee:

I am Heather Cianfrocco, CEO of Optum Rx, a part of UnitedHealth Group. I appreciate the opportunity to address the vitally important topic of the cost and accessibility of insulin. While meaningful progress has been made through both private sector and government actions, more can be done to close the remaining gaps in consistent, affordable access to insulin for everyone who needs it.

Our customers – employers, unions, health plans, and governments – count on us to help them access the most effective medicines at the most affordable cost. Our team of pharmacists, pharmacy technicians, clinicians, and health care professionals works every day to improve health outcomes and simplify the health system for consumers. It is important to note that companies like ours are the only link in the drug supply chain that exists to reduce costs.

My testimony focuses on three areas:

- 1. How our Company makes prescription drugs more accessible and affordable and improves health outcomes for patients.**
- 2. Actions our Company has taken to make insulin more affordable.**
- 3. Policy solutions to make insulin and other prescription drugs more affordable for people and more sustainable for the country.**

How Our Company Makes Prescription Drugs More Accessible and Affordable and Improves Health Outcomes

Our Company’s role is to ensure patients have access to the prescription drugs they need while managing the cost of those drugs. Companies like ours act as a counterweight to the substantial market and pricing power of drug manufacturers, which have the sole discretion in setting prices for their products. Under loopholes in the current patent system, periods of product exclusivity can be extended by manufacturers and product competition limited for decades, amounting to government-granted monopolies. This makes our role even more critical.

Thousands of employers of all sizes rely on our negotiations and the resulting savings off of high and increasing drug list prices. Our negotiated discounts and clinical tools

deliver approximately \$1,600 in average annual drug savings per person. A recent paper by a University of Chicago economist concluded that without these negotiations with manufacturers, the cost of drugs would be even higher. In fact, this research shows Pharmacy Benefit Managers (PBMs) save the system \$145 billion annually.¹ Our customers rely on our essential services and these material drug cost savings to control medical and pharmacy benefit costs for their employees and members. Moreover, the role we play is more important than ever with the advent of exceptionally high-priced specialty drugs, a large and growing piece of the prescription drug market in which competition is lacking, and many manufacturers offer no discounts.

Our customers recognize the value of our services, which are provided in a highly competitive market. As of 2021, there were 70 companies that offered a full range of pharmacy benefit services in the U.S. market.² We must compete day in and day out to win and retain our customers. We face competition from pharmacy benefit companies of varying sizes with different value propositions – some of which are growing disruptors in the market. We are constantly innovating to drive costs lower and meet the unique needs and demands of current and prospective customers.

We compete for business on our clinical capabilities, patient support programs, drug trend analytics and insights, but most importantly on our ability to lower drug costs for our clients, regardless of list price. This squarely aligns the interests of pharmacy benefit companies with our clients and our consumers, not with the manufacturers that set the prices for prescription drugs.

Optum Rx plays four essential roles in serving customers and consumers.

First, everything we do begins with a clinical foundation. Our work is anchored by clinical data and starts with our independent Pharmacy & Therapeutics (P&T) Committee, which applies significant clinical rigor and provides unbiased, evidence-based review and appraisal of new and existing drugs and their place in therapy. Our P&T Committee is made up of physicians, nurses, and pharmacists who are not affiliated with Optum Rx and operates in a highly transparent manner. Our customers are welcome to observe the P&T Committee's clinical decision-making process.

Second, once we have completed our clinical assessment, we aggressively negotiate with drug manufacturers to secure the lowest net cost for our customers to enable them to control costs for their members. Although more than 90 percent of prescriptions are for low-cost generics, often without rebates,³ negotiated discounts are the only check on manufacturers' pricing power for most branded drugs (the remaining 10 percent of

¹ Casey Mulligan. "The Value of Pharmacy Benefit Management." July 2022. Available at: https://bfi.uchicago.edu/wp-content/uploads/2022/07/BFI_WP_2022-93.pdf

² PCMA. "The Highly Competitive PBM Marketplace." April 2021. Available at: <https://www.pcmamet.org/highly-competitive-pbm-marketplace/>

³ Food and Drug Administration. "Office of Generic Drugs 2021 Annual Report." Available at: <https://www.fda.gov/drugs/generic-drugs/office-generic-drugs-2021-annual-report#:~:text=Currently%2090%20percent%E2%80%94%20out,they%20are%20on%20the%20market.>

prescriptions). While negotiating for discounts on these expensive branded drugs is a vital role, it is only one of the ways we work to ensure people have access to the most affordable medicines. We offer our customers a wide range of formularies, which enables them to choose the solution that best fits their needs and meets their affordability, predictability, and transparency expectations.

Third, we provide a range of options for providing the prescription drug benefit that meets the needs of our diverse employer, union, health plan, and government customers. While our customers ultimately determine their medical and pharmacy benefit design, we offer benefit plans that balance their health care cost affordability with patient out-of-pocket cost protections, such as our \$35 insulin and critical drug affordability program. We also offer our customers choice in how they compensate us for the savings we generate and reimburse us for pharmacy claims administered by our pharmacy network. Some customers choose to compensate us for the savings we generate and the services we provide by opting for us to retain a small fraction of the discounts we negotiate with pharmaceutical manufacturers. Other customers prefer that we pass along to them 100% of the savings we negotiate and instead compensate us via administrative fee. Some reimburse us for pharmacy network claims through a predictable, aggregate payment and some choose a per claim or “pass through” reimbursement. Our clients are provided options and they each make the choice that best meets their needs. On average, Optum Rx passes through 98% of the discounts and the pharmacy rates we negotiate to our customers. These savings enable them to reduce premiums, provide point-of-sale discounts, and invest in population health and wellness programs.

A key underpinning of this process is Optum Rx’s ability to achieve the lowest net cost for our customers for the benefits they provide – through a combination of negotiating both discounts with manufacturers and reimbursement with a network of pharmacies where members fill their prescriptions. The essential value we deliver is validated by each of the employer, union, health plan, and government customers who have selected us as their PBM. For this service, our fees equate to 2% of these savings, which covers the administrative functions of negotiation, formulary management, pharmacy network management, credentialing, payment, auditing, and reporting. After performance of these functions – and all the clinical, claims, client, provider, and patient related benefit administrative functions, our Optum Rx margin was roughly 4% in 2022.

Fourth and finally, we deploy innovative clinical support programs to actively support the patients we serve at each stage of their health care journey, as well as tools to drive affordability. Our PreCheck MyScript tool enables health care providers and patients to see how much a prescription will cost – and if there are any lower cost alternatives – before leaving a provider’s office. Our Price Edge tool ensures patients pay the lowest cost in the market for their prescription and has already saved patients more than \$4 million since the program launched in January. We also offer condition-specific medication adherence programs to make sure patients stay on therapy once prescribed. All these tools help people cut through the complexity that can be a barrier to accessing affordable, high-quality care.

Actions Our Company Has Taken to Make Insulin More Affordable

Diabetes is the eighth leading cause of death in the United States.⁴ More than 37 million people, or 11.3 percent of the U.S. population has diabetes.⁵ Diabetes leads to decreased life expectancy and higher health care costs. The appropriate management of diabetes may encompass a range of interventions for patients, including insulin for those who depend on it.

Insulin was discovered more than a century ago and it has now been 23 years since long-acting insulin was first made available to patients.⁶ Since that time, little significant clinical advancement has been made, but insulin manufacturers have continued to raise prices due to pricing power and insufficient competition.

Loopholes in U.S. patent law enable pharmaceutical manufacturers to continue extending patent protection for a drug well beyond its original date through tactics such as product hopping, where manufacturers attempt to switch patients to new formulations of their products before losing exclusivity. This action results in higher prices that directly impact patients. As another example of efforts to delay competition, one insulin manufacturer accumulated more than 70 secondary patents to block biosimilar competition.⁷ Only after significant litigation and a change in the approval pathway for insulin biologics were competitors able to come to market. Moreover, as noted in the Senate Finance Committee's 2019 Report on the insulin market, many of the secondary patents filed for insulin are related to mechanisms for delivery (e.g., pens and auto-injectors) – not the medicine itself.⁸ This finding raises important questions about what kind of innovation current patent law is encouraging.

The Senate Finance Committee Report also found insulin manufacturers raise prices in lockstep with one another – a practice known as “shadow pricing.” This practice has resulted in a lack of price differentiation and high insulin list prices with no connection to the rate of health care inflation or the cost of goods. This historical insulin pricing serves as a case study for harmful manufacturer pricing strategies. Shadow pricing exists because of manufacturers' sole control of the price of their products and a lack of meaningful competition in the insulin market.

⁴ Centers for Disease Control and Prevention, National Center for Health Statistics. Available at: <https://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm>

⁵ Centers for Disease Control and Prevention. “National Diabetes Statistics Report: Estimates of Diabetes and Its Burden in the United States.” Available at: <https://www.cdc.gov/diabetes/data/statistics-report/index.html>

⁶ Food and Drug Administration. “100 Years of Insulin.” Available at: <https://www.fda.gov/about-fda/fda-history-exhibits/100-years-insulin>

⁷ Initiative for Medicines, Access and Knowledge (I-MAK), “Overpatented, Overpriced, Special Edition: Lantus.” October 2018. Available at: <http://www.i-mak.org/wp-content/uploads/2018/10/I-MAK-Lantus-Report-2018-10-30F.pdf>

⁸ See footnote 4, U.S. Senate Committee Finance. “Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug.” January 2021. Available at: <https://www.finance.senate.gov/download/grassley-wyden-insulin-report>

In the last several years, with leadership from Congress and action in the private sector, meaningful progress has been made in making insulin more affordable in Medicare and the commercial market. Last year, UnitedHealthcare was the first to implement zero-dollar cost sharing for insulin for its fully insured members. The Medicare Part D \$35 monthly out-of-pocket cap on insulin that went into effect this year is providing certainty to all seniors in Part D. The recent announcements by some drug manufacturers that they will lower their list prices on some insulin products in advance of the approaching removal of the cap on Average Manufacturer Price rebates in Medicaid was a welcome development and confirms that drug manufacturers alone have the power to set and raise prices. They also have the power to lower them when it is in their interests to do so. Policies that discourage list price increases help reduce drug costs to customers and consumers.

We know that when patients have reliable, consistent, and affordable access to needed medications, including insulin, they are better able to adhere to their medications as prescribed, which leads to better health outcomes. Our company has been at the forefront of efforts to improve access to affordable insulin and provide comprehensive care to patients with diabetes:

- Optum Rx negotiates discounts from manufacturers on behalf of our customers and on average passes 98% of the discounts through to them, which allows them to keep premiums low, improve benefits, or lower out-of-pocket costs for patients.
- We began offering point-of-sale discounts on insulin and other rebated drugs to fully insured group customers in 2018.
- As part of the company's initiative to make critical and life-saving drugs more affordable, in July 2022, UnitedHealthcare eliminated out-of-pocket costs in its standard fully insured group plans for preferred short- and long-acting insulins as well as EpiPens, Albuterol and Naloxone.⁹ Offering these preferred drugs at \$0 cost share builds on our previous actions, including point-of-sale discounts, that have delivered millions of dollars of savings directly to consumers at the pharmacy counter.
- We have placed insulin on our Preventive Drug List, given the important role insulin plays in preventing the development of additional health conditions. These drugs are available at a reduced out-of-pocket cost to patients with preventive drug benefits through their health plans. This action is particularly important for patients enrolled in high-deductible health plans in the commercial market and has driven more than \$14 million in patient out-of-pocket savings on drugs in the first quarter of 2023 alone.
- In addition, for new clients, our standard recommended benefit caps out-of-pocket costs for the preferred insulin at \$35, and for customers in high-deductible plans, our plan clients have the option to bypass the deductible and apply their rebates to the customer's co-insurance obligation at the point of sale.

⁹ "UnitedHealthcare To Eliminate Out-of-Pocket Costs on Several Prescription Drugs, Including Insulin, for Eligible Members." July 2022. Available at: <https://newsroom.uhc.com/news-releases/uhc-eliminate-out-of-pocket-costs.html>

- We were active partners in the CMS Medicare Part D Demo Model that piloted \$35 insulin. The program rolled out to all Part D beneficiaries in 2023.
- Through our integrated pharmacy and clinical care services, we provide comprehensive chronic care management to patients with diabetes. Patients have access to pharmacists and pharmacy technicians - 24 hours a day, seven days a week - who provide face-to-face or virtual consultations and coaching to help patients manage diabetes and other chronic conditions. More than half of the patients in our Diabetes Management Program experienced improved A1C levels.
- Working with Sanofi, we offer a monthly supply of insulin for \$35 for uninsured individuals.
- As a result of these efforts, our 1.7 million consumers who take insulin now pay an average of \$22 per month – and our efforts are ongoing.

Manufacturers have blamed companies like ours, along with health plans and hospitals, for high drug prices. They contend that the discounts we negotiate with them are the root cause of the problem. However, drug prices are rising fastest on specialty drugs, where manufacturers are less willing to negotiate discounts due to the lack of clinical alternatives or other meaningful competition. It is no surprise, then, that CMS reported that in 2016 and 2017, prices increased the most for drugs with only one manufacturer.¹⁰ Additionally, economist Alex Brill concluded that list prices of rebated and non-rebated drugs have been increasing at comparable rates – dispelling the myth that discounts negotiated by companies like ours are responsible for the list prices set and raised unilaterally by drug manufacturers.¹¹

Policy Solutions to Make Insulin and Other Prescription Drugs More Affordable for People and More Sustainable for the Country.

While progress has been made in promoting insulin affordability, more can be done. Our company strongly supports policy solutions that will fill in gaps, increase competition among manufacturers, and ensure all patients – regardless of their coverage situation – can access this lifesaving medicine.

As mentioned earlier, under federal law cost sharing for covered insulins in Medicare is now capped at \$35 for a month’s supply. A similar approach in the commercial market would close the gap for Americans who still cannot consistently afford insulin. Importantly, such a cap must preserve the ability for pharmacy benefit companies to negotiate for the lowest cost of insulins for our customers. Even with those welcomed list price reductions by some manufacturers on some insulins, the list price of insulin is still above \$35. Taking this approach in the commercial market would protect patients at the pharmacy and ensure employers, plans, unions, and governments can still obtain the lowest net cost for insulin.

¹⁰ Sarah Karlin-Smith, Sarah Oweremohle, and Janie Boschma. “Drugs with a single manufacturer drive Medicare, Medicaid, spending increases, CMS says.” Politico, March 2019.

¹¹ Alex Brill. “Understanding Drug Rebates and Their Role in Promoting Competition.” March 2022. Available at: https://www.affordableprescriptiondrugs.org/app/uploads/2022/02/CAPD-Brill-Report_FINAL.pdf

Beyond insulin, broader reforms are needed to make all prescription drugs more affordable for people and sustainable for the country. This starts with creating more competition in drug manufacturing.

We are most effective in negotiating with manufacturers to achieve savings when competition exists. To that end, public policies are needed that both encourage competitors to enter the market and end the widespread use of manufacturer practices that actively prevent competition and extend patent protections for medicines far longer than originally intended.

Congress should address abuses of the patent system that prolong a drug's market exclusivity and delay the entrance of generic and biosimilar therapies. While patents play an important role in ensuring manufacturers earn a return on a successful drug, current law allows manufacturers to exploit loopholes and extend these protections for no other purpose than greater profit. Manufacturers' ability to build "patent thickets" around products and engage in pay-for-delay and product hopping schemes should be prohibited. To prevent these and other abuses, a 10-year cap on a product's exclusivity should be established – regardless of the number of patents associated with it. Additional support should also be given to the Patent and Trademark Office to ensure it has tools to identify and invalidate weak or superfluous pharmaceutical patents in a timely manner.

Finally, we continue to support efforts to expand value-based arrangements between payors and pharmaceutical manufacturers. The flexibilities offered by these models can speed access to new therapies, ease budgetary pressures on health systems, and ensure health care dollars are spent on treatments that work. The federal government can advance these goals by adopting more modernized price reporting requirements in Medicare and Medicaid and allowing greater flexibility in the Medicare benefit to enable cost sharing structures that reflect value-based pricing arrangements.

In conclusion, we appreciate the opportunity to share with the Committee the meaningful steps we have taken and will continue to take to make insulin more affordable for patients we serve. We are committed to doing our part to make insulin and all prescription drugs more affordable and to improve health outcomes while enhancing the consumer experience.